Label, IN Part: (Bag) "Magnatone Supplement Minerals Vitamins for the Dairy Herd \* \* \* Vitamin A (Carotene from Carrot Oil) 25,000 U. S. P. Units per lb., Vitamin D<sub>2</sub> (Irradiated Ergosterol \* \* \* 10,000 U. S. P. Units per lb. \* \* \* Ingredients Cottonseed Oil Meal; Linseed Oil Meal; Soybean Oil Meal, Dehydrated Alfalfa Meal; Distillers Solubles; Carrot Oil, Irradiated Ergosterol; Thiamine Chloride; Riboflavin; Nicotinic Acid; Calcium Carbonate; Steamed Bone Meal; Di-Calcium Phosphate; Tri-Calcium Phosphate (from defluorinated rock phosphate); Magnesium Carbonate; Magnesium Sulfate; Manganese Sulfate; Copper Sulfate; Iron Oxide; Zinc Sulfate; Potassium Iodide; Sodium Chloride (Salt); Cobalt Sulfate and Sodium Tetraborate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in accompanying booklets entitled "Magnatone Bulletin Volume 1," "Magnatone Health Products," and "The Magnatone Health Program," were false and misleading. The statements represented and suggested that the article was effective to prevent starvation and thereby assure completion of a normal life cycle, barring unnatural climatic conditions and accidents; to give vibrant health and full stamina and endurance; to confer disease resistance and perfect health; to remedy most livestock diseases, including mastitis, white scours of calves, shy breeding, and many other familiar disorders erroneously stated to be due to starvation; to condition quickly and rehabilitate the herd; to remedy anorexia (depressed appetite) and pneumonia; to revitalize quickly the digestive and metabolic systems of animals to operate at maximum capacity and efficiency; to assure freedom from disease and resistance to infections; to remedy injury to the nervous system; to insure against failure to grow; to treat yellow liver and anemia; to prevent death; to remedy fatty liver, cirrhosis of the liver, and disturbance of lactation and growth; to influence favorably production and growth of animals; to prevent sterility in animals of both sexes; and to effect phenomenal increases in milk production. The statements further represented that the article was effective against convulsions, kidney degeneration, sterility, abortions, birth of dead or weak calves, bone diseases, and paralysis. The article was not effective for the purposes represented.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 25, 1952. Default decree of condemnation. The court ordered that the product be delivered to a Federal institution, for use as animal feed.

In attempting to execute the order of the court, the United States marshal found that the product under seizure had been returned to the State of Ohio, where it was fed to animals. Upon submission of these facts to the court, an order was entered on June 19, 1952, dismissing the libel.

3760. Misbranding of veterinary products. U. S. v. 22 Packages, etc. (F. D. C. No. 32548. Sample Nos. 29279-L to 29286-L, incl., 29290-L.)

LIBEL FILED: February 26, 1952, Eastern District of Washington.

ALLEGED SHIPMENT: On or about August 7 and November 19, 1946, September 3, 1947, June 23 and October 21, 1948, May 26, August 12, and November 13, 1950, January 18, March 22, and July 23, 1951, and other dates unknown, by the C. U. McClellan Laboratories Corp., from Los Angeles, Calif.

Product: 14 1¼-pound packages and 10 5-pound packages of McClellan's Cow Compound; 18 packages of McClellan's Pullet Size Nic-Ka-Mal; 15 packages of McClellan's Adult Size Nic-Ka-Mal; 28 2½-ounce packages and 41 8-ounce packages of McClellan's Nicotine Krumbles; 6 4-pound cartons of McClellan's Phenothiazine Powder; 14 4-ounce bottles, 24 8-ounce bottles, 18 32-ounce bottles, and 1 1-gallon bottle of McClellan's Rex Liquid; 92 1½-pound packages and 11 5-pound packages of McClellan's Rex Poultry Powder; and 24 1-quart bottles, 55 8-ounce bottles, and 44 16-ounce bottles of McClellan's Inhalant, at Spokane, Wash. A booklet entitled "1950 Price List" accompanied the products.

LABEL, IN PART: "McClellan's Cow Compound \* \* \* Ingredients: Elecampane Root, Uva Ursi Leaves, Spearmint Leaves, Black Haw Bark, Ginger Root, Red Pepper, Aletris Root, Foenugreek Seed, Witch Hazel Leaves, Boneset Herb, Damiana Herb, Salt, Red Oxide of Iron, Epsom Salts"; "McClellan's Nic-Ka-Mal \* \* \* Pullet Size Contains 100 71/2-Grain Tablets [or "Adult Size Contains 100 15-Grain Tablets"] \* \* \* These tablets contain Nicotine sulfate as Alkaloid 5%, Extract of Kamala 15%, Powdered Kamala 38%, Calcium Phosphate combined with inactive Acacia and Cerelose"; "McClellan's Nicotine Krumbles Active Ingredient Against Worms: Nicotine Sulfate expressed as Alkaloid for Nicotine 5%. Inert ingredients: Iron Sulfate, Rosin, Charcoal and Diatomaceous"; "McClellan's Phenothiazine Powder \* \* \* Active Ingredient: Phenothiazine 100%"; "McClellan's Rex Liquid \* \* \* Contains the following ingredients: Iron Sulfate, Epsom Salts, Glauber Salts, Salt, Lactic Acid, Benzoate of Soda, Quassia, Oil of Anise, Potassium Iodide, Red Pepper"; "McClellan's Rex Poultry Powder \* \* \* Contains: Ground Limestone, Salt, Epsom Salts, Bone Meal, Sulfur, Iron Sulfate, Red Oxide of Iron, Manganese Sulfate, Charcoal, Salt Peter, Quassia, Anise Seed, Gentain, Soda Bicarbonate, Potassium Iodide, Copper Sulfate, Cobalt Chloride"; "McClellan's Inhalant \* \* \* Contains: Oil of Camphor, Oil of Eucalyptus, Menthol Crystals, Thymol Crystals, Pine Oil, Mineral Oil."

NATURE OF CHARGE: McClellan's Pullet Size Nic-Ka-Mal. Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that the article was effective to control large roundworm infestation of poultry and was beneficial in parasitism caused by tapeworms in poultry were false and misleading since the article was not effective and was not beneficial in the conditions represented; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions in its labeling for the treatment of pullet-size birds provided insufficient medication to effectively expel large roundworms from pullets.

McClellan's Nicotine Krumbles. Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that the article was effective to control parasitism (large roundworms) in flocks of chickens and turkeys were false and misleading since the article was not effective for such purpose; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions in its labeling for the treatment of 200 pullets would supply insufficient medication to effectively expel large roundworms from 200 pullets.

McClellan's Cow Compound, McClellan's Adult Size Nic-Ka-Mal, McClellan's Rex Liquid, McClellan's Rex Poultry Powder, McClellan's Inhalant, and Mc-Clellan's Phenothiazine Powder. Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading. The statements represented and suggested that the Cow Compound was effective to restore cows to a normal healthy condition regardless of their condition before using the product; that the Adult Size Nic-Ka-Mal was effective to control large roundworm infestation in poultry and was beneficial in parasitism (tapeworms); that the Rex Liquid was effective for disease conditions of poultry characterized by diarrhea; that the Rex Poultry Powder was effective as a tonic and conditioner; that the Inhalant was effective against disease conditions of the throat and nostrils of poultry, and that its use as an inhalant or spray was an effective treatment of respiratory diseases of poultry; and that the Phenothiazine Powder, by removing cecal worms from poultry, was effective to prevent blackhead in turkeys, and that the article was effective to remove any variety of intestinal and stomach worms from poultry. The articles were not effective for the purposes and conditions stated and implied, and they were not capable of fulfilling the promises of benefit made for them.

DISPOSITION: April 14, 1952. Default decree of condemnation and destruction.

## INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3741 TO 3760

#### PRODUCTS N. J. No. N. J. No. McClellan's Cow Compound, Mc-3754 Adhesive bandages\_\_\_\_\_ Clellan's Pullet Size Nic-Kaalpha-tocopheryl, d-, acetate cap-Mal, McClellan's Adult Size sules \_\_\_\_\_ 3747 Nic-Ka-Mal, McClellan's Nic-Amphetamine, dextro-, sulfate otine Krumbles, McClellan's 3743 tablets \_\_\_\_\_ Phenothiazine Powder, Mc-3757 Arthrid \_\_\_\_\_\_ Clellan's Rex Liquid, McClel-Arthritis, remedies for. See lan's Rex Poultry Powder, Rheumatism, remedies for. and McClellan's Inhalant\_\_\_ 3760 3753 Arvimin \_\_\_\_\_ Magnatone Supplement\_\_\_\_\_ 3759 Bandages, adhesive\_\_\_\_\_ 3754 Mendaco \_\_\_\_\_\_ 3756 3749 Belladonna, tincture of\_\_\_\_\_ Mer-I-Col iron tonic...---3758 Conjugated estrogen tablets\_\_\_\_ 3752 Nic-Ka-Mal, McClellan's Pullet 3760 Cow Compound, McClellan's\_\_\_\_ Size and McClellan's Adult 3756 Cystex -----3760 Size\_\_\_\_\_ d-alpha-tocopheryl acetate cap-Nicotine Krumbles, McClellan's\_ 3760 3747 sules \_\_\_\_\_ Penicillin G, procaine, in aqueous 3741 Devices \_\_\_\_\_ suspension \_\_\_\_\_ 3750 Dextro-amphetamine sulfate tab-Pentobarbital sodium capsules\_\_ 3745 3743 lets\_\_\_\_\_ Phenobarbital tablets\_\_\_\_\_ 3745 3746 Donnatal tablets\_\_\_\_\_ Phenothiazine Powder, McClel-Estrogenic substance\_\_\_\_\_ 3752 lan's \_\_\_\_\_ 3760 Hope mineral tablets\_\_\_\_\_ 3748 Posterior pituitary injection\_\_\_\_ 3751 3749 Hyoscyamus, tincture of\_\_\_\_\_ Procaine penicillin G in aqueous 3760 Inhalant, McClellan's\_\_\_\_\_ 3750 suspension \_\_\_\_\_ 3758 Iron tonic, Mer-I-Col\_\_\_\_\_ Rectal disorders, device for\_\_\_\_ Liver injection\_\_\_\_\_ 3755

Issued December 1952.

### FEDERAL SECURITY AGENCY

### FOOD AND DRUG ADMINISTRATION

# NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3761-3780

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs. Washington, D. C., December 18, 1952.

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<sup>\*</sup>For presence of a habit-forming narcotic without warning statement, see Nos. 3762-3764, 3766; omission of, or unsatisfactory, ingredients statements, Nos. 3761, 3777; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3761-3766; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3762, 3764-3766; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3768.

# DRICS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3761. Misbranding of sulfathiazole tablets. U. S. v. Hugh Allen (Hugh Allen, Druggist). Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 31562. Sample Nos. 3180-L, 3181-L.)
- INFORMATION FILED: April 21, 1952, Northern District of West Virginia, against Hugh Allen, trading as Hugh Allen, Druggist, Petersburg, W. Va.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of West Virginia of quantities of sulfathiazole tablets.
- ALLEGED VIOLATION: On or about May 10 and 15, 1951, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged drug was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the repackaged drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drug failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users.
- DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.
- 3762. Misbranding of Seconal Sodium capsules. U. S. v. Andrew Kolanowski. Plea of guilty. Fine, \$100. (F. D. C. No. 32746. Sample No. 9420-L.)
- INFORMATION FILED: April 25, 1952, Northern District of Illinois, against Andrew Kolanowski, an assistant pharmacist for Marshall Drugs, Chicago, Ill.
- Alleged Violation: On or about April 5, 1951, while a number of Seconal Sodium capsules were being held for sale at Marshall Drugs, after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the drug being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."